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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/266,803	03/12/1999	GREGORY M. GLENN	PM-256865	6258

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No. 09/266,803	Applicant(s) GLENN ET AL.	
	Examiner G. R. Ewoldt, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 112,115-123,125,126,129-131 and 134-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 112,115-123,125,126,129-131 and 134-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, remarks, and Terminal Disclaimer, filed 12/21/04, are acknowledged. In view of the amendments, the previous rejections under the first paragraph of 35 U.S.C. 112 have been withdrawn. In view of the amendments, and the Terminal Disclaimer, the previous rejections for obvious-type double patenting over U.S. Application No. 09/337,746 and U.S. Application No. 10/633,626 have been withdrawn.

2. Claims 112, 115-123, 125-126, 129-131, and newly added Claims 134-149, are pending and under examination. Note that new Claim 134 is misidentified as "previously presented".

3. The following are new grounds for rejection necessitated by Applicant's amendment and submission of an additional application.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 135-149 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a method employing a formulation comprising "at least one adjuvant, wherein said formulation does not comprise transferosomes; wherein said formulation is hydrated such that delivery of an effective amount of said antigen occurs, wherein said effective amount of said antigen induces said immune response" (Claim 135),

B) a method wherein "hydration is accomplished by application of a patch" (Claims 136 and 148),

C) a method employing a formulation comprising "a pertussis toxin toxoid having adjuvant activity, ... a CT toxoid having adjuvant activity, ... an LT toxoid having adjuvant activity, ...

a Pseudomonas exotoxin A toxoid having adjuvant activity" Claim 145),

D) a method wherein the adjuvant is selected from the group consisting of "an ADP-ribosylating exotoxin in which ADP-ribosyl transferase activity is inactivated; an ADP-ribosylating exotoxin subunit chemically conjugated to a carbohydrate, polypeptide, glycolipid, or glycoprotein antigen, and, an ADP-ribosylating toxoid chemically conjugated to a carbohydrate, polypeptide, glycolipid, or glycoprotein antigen" (Claim 147),

E) a method wherein skin is hydrated by "application of a patch, application of a dressing, application of a cream, emulsion, gel, lotion, ointment, paste, solution or suspension, and, combinations of any of above" (Claim 148).

Applicant states that no new matter has been added and indicates various cites throughout the specification for support.

Regarding A), the specification provide insufficient support for a method comprising the negative limitation, i.e., a formulation without transferosomes, as well as insufficient support for a method employing a formulation that specifically hydrates and induces an antigen-specific immune response as claimed.

Regarding B), the specification does not disclose a patch capable of hydration.

Regarding C), the specification does not disclose the use of the specific toxoids recited in the claims having adjuvant activity.

Regarding D), the specification does not disclose the use of the specific adjuvants recited in the claims conjugated to a carbohydrate, polypeptide, glycolipid, or glycoprotein antigen.

Regarding E), the specification does not disclose a patch, dressing, cream, emulsion, gel, lotion, ointment, paste, solution or suspension specifically for hydration of the skin.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 112, 115-123, 125-126, 129-131, and newly added Claims 134-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1-92 of copending Application No. 10/895,323. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response (TCI) comprising applying a formulation comprising an antigen and an adjuvant including hydrating the skin and numerous other obvious permutations of the claimed method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


8. Applicant is reminded of the duty to disclose all information relevant to patentability. As set forth in Applicant's declaration, Applicant acknowledges a responsibility under 37 CFR 1.56 to disclose all information known to Applicant material to patentability. Clearly, the disclosure of new applications reciting related claims falls under said responsibility.

9. No claim is allowed.

10. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.


2/2/05

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600